

**Amendments To The Claims:**

This listing of claims will replace all prior versions, and listings, of claims in the application:

**In the Claims:**

1. (Original) A method of treating a CNS disorder which comprises orally administering to a patient a therapeutically effective amount of lamotrigine or a pharmaceutically acceptable derivative thereof in the form of a sustained release formulation.
2. (Original) A method as claimed in claim 1 wherein the lamotrigine or a pharmaceutically acceptable derivative is present in the range of 1 to 500 mg.
3. (Currently Amended) A method as claimed in claim 1 ~~or 2~~ wherein substantially all the lamotrigine or a pharmaceutically acceptable derivative is released from the formulation in a period of 2 to 20 hours after administration to a patient.
4. (Currently Amended) A method as claimed in ~~any one of~~ claims 1 ~~to 3~~ wherein the administration is once a day.
5. (Currently Amended) A method as claimed in ~~any one of~~ claims 1 ~~to 4~~ wherein a reduction in the adverse ~~effect~~ event profile is achieved.
6. (Currently Amended) A method as claimed in ~~any one of~~ claims 1 ~~to 5~~ wherein the CNS disorder is selected from epilepsy; pain; oedema, multiple sclerosis or schizophrenia.
7. (Currently Amended) A method as claimed in ~~any one of~~ claims 1 ~~to 5~~ wherein the CNS disorder is a psychiatric indication.
8. (Currently Amended) A method as claimed in ~~any one of~~ claims 7 wherein the psychiatric indication is bipolar disorder.

9. (Original) A method of reducing the incidence of at least one adverse event associated with the administration of lamotrigine or a pharmaceutically acceptable derivative thereof, which method comprises orally administering to a patient a therapeutically effective amount of lamotrigine or a pharmaceutically acceptable derivative thereof in the form of a sustained release formulation.

10. (Original) A sustained release formulation of lamotrigine or a pharmaceutically acceptable derivative thereof.

11. (Original) A sustained release formulation as claimed in claim 10 wherein substantially all the lamotrigine or a pharmaceutically acceptable derivative thereof is released from the formulation 2 to 20 hours after administration to a patient.

12. (Currently Amended) A sustained release formulation as claimed in claim 10 ~~or 11~~ which has an *in vitro* dissolution profile in which 40 to 65 % of the lamotrigine is dissolved in 3 to 8 hours.

13. (Currently Amended) A sustained release formulation as claimed in ~~any one of~~ claims 10 ~~to 12~~ which has an *in vitro* dissolution profile as shown in or substantially similar to any one of Figures 3, 4 or 5.

14. (Currently Amended) A sustained release formulation as claimed in ~~any one of~~ claims 10 ~~to 13~~ which has an *in vitro* dissolution profile wherein the Area Under the Curve value is between 80% and 125% to that of any one of Figures 3, 4 or 5.

15. (Original) A sustained release formulation of lamotrigine or a pharmaceutically acceptable derivative thereof in which there are at least two phases in the release of lamotrigine or a pharmaceutically acceptable

derivative thereof, wherein the release rate in the first phase is different from the release rate in the second phase.

16. (Currently Amended) A sustained release formulation as claimed in ~~any one of claims 10 to 12 and 15~~ which has an *in vitro* dissolution profile as shown or substantially similar to that shown in Figure 6.

17. (Currently Amended) A sustained release formulation as claimed in ~~any one of claims 10 to 12 and 15~~ which has an *in vitro* dissolution profile wherein the Area Under the Curve value is between 80% and 125% to that of Figure 6.

18. (Original) A sustained release formulation as claimed in claim 10 wherein the formulation is a functional coated tablets or caplets, or time-release tablets or caplets matrices containing wax or polymer, or osmotic pump devices or combinations thereof.

19. (Original) A sustained release formulation as claimed in claim 18 which is a matrix tablet.

20. (Currently Amended) A sustained release as claimed in claim ~~20~~ 18 wherein the formulation comprises;

- a) 2.5 to 80% by weight lamotrigine or a pharmaceutically acceptable derivative thereof;
- b) 10 to 70% by weight release retarding polymer;
- c) 0 to 70 % by weight diluent;
- d) 0 to 20 % by weight compression aid; and
- e) 0.1 to 2.5% by weight lubricants.

21. (Currently Amended) A sustained release formulation claimed in ~~any one of claims 18 to 20~~ wherein the formulation comprises

- a) 8.3 to 50 % by weight lamotrigine or a pharmaceutically acceptable derivative thereof;

- b) 17.5 to 66.3 % by weight Methocel E4MP, CR Grade, POLYOX WSRN-80 or Methocel, K100LV or a mixture thereof;
- c) 25 to 60 % by weight lactose; and
- d) 0.1 to 0.4 % by weight magnesium stearate.

22. (Currently Amended) A sustained release formulation as claimed in ~~any one of claims 10 to 14, 18 to 21~~ which upon administration to a human produce a AUC values of 80 to 125% and a  $C_{max}$  being of about 30% less than an instant release tablet containing the same amount of lamotrigine or a pharmaceutically acceptable derivative thereof.

23. (Original) A sustained release formulation as claimed in claim 18 which is a DiffCORE tablet.

24. (Currently Amended) A sustained release formulation as claimed in claims 10 to ~~12~~ ~~16 to 18~~ and 23 comprising

1) a core comprising lamotrigine or a pharmaceutically acceptable derivative thereof:

2) an outer coating covering said core, the thickness of said outer coating being adapted such that it is substantially impermeable to the entrance of an environmental fluid and substantially impermeable to the exit of lamotrigine or a pharmaceutically acceptable derivative thereof, and

3) said outer coating including one or more orifices extending from the outside of the coating substantially completely through said coating but not penetrating said core allowing the release of lamotrigine or a pharmaceutically acceptable derivative thereof from the core into environmental fluid, said orifices having an area or combined area from about 10 to about 60 percent of the face area of said formulation, wherein the release of lamotrigine or a pharmaceutically acceptable derivative thereof occurs substantially through said orifice.

25. (Currently Amended) A sustained release formulation as claimed in claim 23 wherein the release of lamotrigine or a pharmaceutically acceptable derivative thereof is via one or more of dissolution, diffusion, osmosis or erosion[.]

26. (Currently Amended) A sustained release formulation as claimed in ~~any one of~~ claims 24 ~~or 25~~ wherein the core further comprises a release retarding excipient.

27. (Currently Amended) A sustained release formulation as claimed in ~~any one of~~ claims 24 ~~to 26~~ wherein the outer coat may dissolve by 0.3 to 5 hours after administration or when the surrounding pH exceeds 5.

28. (Currently Amended) A sustained release formulation as claimed in ~~any one of claims 24 to 27~~ wherein the formulation comprises a core comprising

- a) 2.5 to 80% by weight lamotrigine or a pharmaceutically acceptable derivative thereof;
- b) 17.5 to 70% by weight release retarding polymer;
- c) 0 to 60 % by weight diluent;
- d) 0 to 20 % by weight compression aid; and
- e) 0.1 to 2.5% by weight lubricants and an outer coat comprising
- f) 0.05 mm to 0.30 mm of polymer;

29. (Currently Amended) A sustained release formulation as claimed in ~~any one of claims 24 to 28~~ which upon administration to a human produce AUC values outside the range 80 to 125% and a  $C_{max}$  being of about 30% less than an instant release tablet containing the same amount of lamotrigine or a pharmaceutically acceptable derivative thereof .

30. (Original) A method of achieving a serum concentration wherein upon administration to a patient of a sustained release formulation of lamotrigine or a pharmaceutically acceptable derivative thereof produces area under the curve values of 80 to 125% and a  $C_{max}$  being of about 30% less than an instant release tablet containing the same amount of lamotrigine or a pharmaceutically acceptable derivative thereof.

31. (Original) A method of achieving a serum concentration wherein upon administration to a patient of a sustained release formulation of lamotrigine or a pharmaceutically acceptable derivative thereof produces area under the curve values outside the range of 80 to 125% and a  $C_{max}$  being of about 30% less than an instant release tablet containing the same amount of lamotrigine or a pharmaceutically acceptable derivative thereof.

32. (New) A sustained release formulation as claimed in claim 15 which has an *in vitro* dissolution profile as shown or substantially similar to that shown in Figure 6.

33. (New) A sustained release formulation as claimed in claim 15 which has an *in vitro* dissolution profile wherein the Area Under the Curve value is between 80% and 125% to that of Figure 6.